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|--|-------------|----------------------|--------------------------------|------------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO.       |
| 10/611,582   | 07/01/2003  | Rajneesh Taneja      | ABB01259P00330US<br>(6951.US)  | 5225                   |
| 7590 10/29/2008<br>TAP Pharmaceutical Products, Inc.<br>Attention: Mark J. Buonaiuto<br>675 North Field Drive<br>Lake Forest, IL 60045 |             |                      | EXAMINER<br>MERCIER, MELISSA S |                        |
|  |             |                      | ART UNIT<br>1615               | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>10/29/2008        | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                       |   |  |
|------------------------------|---------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/611,582  | <b>Applicant(s)</b><br>TANEJA, RAJNEESH |  |
|                              | <b>Examiner</b><br>MELISSA S. MERCIER | <b>Art Unit</b><br>1615                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Summary**

Receipt of Applicants Remarks and Amended Claims filed on August 4, 2008 is acknowledged. Claims 1-8 remain pending in this application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (WO 01/51050).

Phillips discloses a liquid oral pharmaceutical composition for the suppression of gastric acid secretion, prepared by mixing omeprazole or another proton pump inhibitor or derivative thereof with a solution including at least one buffering agent (page 29, lines 22-31). Lansoprazole is disclosed (page 30, lines 7-10). Examples of buffering agents include sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium glucomate, for example (page 30, line 29 through page 31, line 17). Various additives can be added to enhance stability, sterility, or isotonicity (page 32, lines 26-28). Thickening agents such as methylcellulose may be used to reduce the settling of the omeprazole or other PPI from the suspension (page 33, lines 6-11).

Phillips further discloses the pharmaceutical composition comprising the PPI and at least one buffering agent in a form convenient for storage, whereby when the composition is placed into an aqueous solution, the composition dissolves yielding a

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suspension suitable for enteral administration to a subject. The composition is a solid form prior to dissolution or suspension in an aqueous solution (page 33, lines 17-29). The resultant solution is stable at room temperature for several weeks (page 33, lines 30-31). The solution maintains greater than 90% of its potency for 12 months (page 34, lines 1-3). Additionally, it is disclosed that once mixed the resultant solution can be used to provide dosages for a single patient over a course of time, or for several patients (page 34, lines 13-15).

While the viscosity of the composition is not disclosed, it would be obvious to a person of ordinary skill the art to modify the viscosity in order to stabilize the solution and prevent settling of the PPI in the suspension as taught by Phillips in order to prepare an oral suspension for use as a suppressant of gastric acid secretion.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues there is no discussion of sodium bicarbonate having the ability to provide a liquid vehicle or having a pH of 6.5 or greater. While it is acknowledged that Phillips does not disclose the pH of the solution, he does disclose the same composition with the same active agents and buffering agents. pH is considered a property of the composition and therefore, barring a showing to the contrary, one would expect the composition of Phillips to have the same pH as the instant claims. Moreover, Phillips discloses the gastric pH before and after administration of the solution showing an increase in pH, therefore, the pH of the PPI solution has been taught to increase the pH

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of the stomach sufficiently to achieve adequate bioavailability of the drug to effect therapeutic action as applicant has claimed the instantly claimed composition performs.

Applicant additionally argues Phillips does not disclose a uniform suspension. The examiner respectfully disagrees. Phillips discloses the composition is in the form of a solution or suspension. The solution is stable for several weeks. Therefore, it is the position of the examiner that the solution would be uniform. Phillips additionally discloses percentages of each component that can be present and the use of thickeners to adjust the viscosity of the solution, therefore, it would have been within the knowledge of the skilled artisan to optimize the percentage of each component to arrive at a solution with the a physiologically acceptable pH range and a palatable viscosity for a solution to be administered enter ally.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615